



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:

WEAVER et al.

Confirmation No.:

6518

Serial No.:

10/665,431

Art Unit:

3733

Filed:

September 22, 2003

Examiner:

James L. Swiger III

For:

**BONE PLATING SYSTEM** 

Attorney Docket No.:

8932-807-999

## INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56 and MPEP § 2001.06(c), applicants hereby provide further information regarding the existence of a litigation associated with the subject U.S. patent application. Said litigation was previously identified in an Information Disclosure Statement filed on March 5, 2007. The subject application and United States Patent No. 7,128,744 ("the '744 patent) are both continuation applications of U.S. Patent Application Serial No. 09/660,287, which issued as U.S. Patent No. 6,623,486 ("the '486 patent"). Both the '486 patent and the '744 patent have recently been asserted in a patent infringement litigation captioned Synthes (U.S.A.) v. Smith & Nephew, Inc., Civil Action No. 03-0084, pending in the U.S. District Court for the Eastern District of Pennsylvania.

Applicants note that this Information Disclosure Statement includes recently-filed pleadings alleging that inequitable conduct was committed during prosecution of the '486 and '744 patents. Those pleadings and the references allegedly forming the basis for the inequitable conduct allegations are submitted herewith. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

| 1. | Enclo | sures accompanying this Information Disclosure Statement are:  |
|----|-------|--|
|    | la.   | A list of all patents, publications, applications, or other information submitted for consideration by the office.   |
|    | 1b.   | A legible copy of:   |
|    |       | Each publication or that portion which caused it to be listed on the PTO-1449;   |
|    |       | For each cited pending unpublished U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion that have been checked to be unavailable at the USPTO's private PAIR system; |
|    |       | An English language copy of search report(s) from a counterpart foreign<br>application or PCT International Search Report;   |
|    |       | Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language  |

|    |             | All other information or portion which caused it to be listed on the PTO-1449.   |
|----|-------------|--|
|    | 1c.         | Pursuant to 37 C.F.R. § 1.98(a)(2)(ii), copies of the cited U.S. patents and U.S. patent application publications are not submitted herewith unless required by the office.  |
|    | ld.         | Pursuant to 1287 OG 163, copies of cited pending unpublished applications that are available at the USPTO's private PAIR system are not submitted herewith.  |
| 2. | $\boxtimes$ | This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b):  Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);  |
|    |             | Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;   |
|    |             | ☐ Before the mailing of the first Office action on the merits;   |
|    |             | Before the mailing of a first Office action after the filing of a request for continued examination under §1.114.  |
| 3. | under 3     | This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the specified in 37 C.F.R §1.97(b), but before the mailing date of any of a final action 17 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that ise closes prosecution in the application.                                       |
|    |             | (Check either Item 3a or 3b)   |
|    | 3a.         | ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.  |
|    | 3b.         | ☐ The \$180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:   |
|    |             | <ul> <li>enclosed.</li> <li>to be charged to Jones Day Deposit Account No. 50-3013.</li> </ul>   |
|    |             | (Item 3b to be checked if any reference known for more than 3 months)  |
| 4. | period      | This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.  |
|    | The Ce      | ertification Statement in Item 5 below is applicable.  |
|    |             | The \$180.00 fee set forth in 37 C.F.R. §1.17(p) is:  — enclosed.  |
| _  |             | to be charged to Jones Day Deposit Account No. 50-3013.  |
| 5. |             | Certification Statement (applicable if Item 3a or Item 4 is checked):  |
|    |             | (Check either Item 5a or 5b)   |
|    | 5a.         | In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. |

|     | 5b.         | cited in a communication from a foreign patent office in a counterpart application, and the communication was not <b>received</b> by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.   |
|-----|-------------|--|
|     | 5c.         | Pursuant to 37 C.F.R. §1.704(d), each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not received by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.   |
| 6.  | $\boxtimes$ | This application is a continuation application under 37 C.F.R. §1.53(b) or (d).  |
|     |             | (Check appropriate Items 6a, 6b and/or 6c)   |
|     | 6a.         | A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently filed herewith.   |
|     | 6b.         | Copies of publications listed on Form PTO-1449 from prior application Serial No. , filed on , of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).  |
|     | 6c.         | Copies of the publications listed on Form PTO-1449 were not previously cited in prior application Serial No. 09/660,287, filed on September 12, 2000, and are provided herewith.   |
| 7.  |             | This is a Supplemental Information Disclosure Statement. (Check Item 7a)   |
|     | 7a.         | This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on . A bona fide attempt was made to comply with 37 C.F.R. §1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental Information Disclosure Statement can be considered as if properly filed on . |
| 8.  | unders      | In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently tood to be the relevance of each non-English language publication is:   |
|     |             | (Check Item 8a, 8b, or 8c)   |
|     | 8a.         | Satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.  |
|     | 8b.         | Set forth in the application.  |
|     | 8c.         | Enclosed as an attachment hereto.  |
| 9.  |             | The Commissioner is authorized to charge any additional fee required or credit any yment for this Information Disclosure Statement and/or Petition to Jones Day Deposit nt No. 50-3013.  |
| 10. | (other      | No admission is made that the information cited in this Statement is, or is considered material to patentability and no representation is made that a search has been made than a search report of a foreign counterpart application or PCT International Search if submitted herewith). 37 C.F.R. §§1.97(g) and (h).  |

## Respectfully submitted,

August 30, 2007 Date:

45,086

(Reg. No.)

Thomas P. Scully JONES DAY

222 East 41st Street

New York, New York 10017

(212) 326-3939

| . ,   | ATTY. DOCKET NO.               | APPLICATION NO. |  |  |
|---|--------------------------------|-----------------|--|--|
| -   | 8932-807-999                   | 10/665,431      |  |  |
| LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary) | APPLICANT WEAVER et al.        |                 |  |  |
| AUG 3 1 2007 y  | FILING DATE September 22, 2003 | ART UNIT 3733   |  |  |

| AL S THO  | DENIDO | <i>y</i>        | U.S. PA          | TENT DOCUMENTS                                     |   |
|-----------|--------|-----------------|------------------|--|---|
| *Examiner |        | Document Number | Date<br>mm/dd/yy | Name of Patentee or Applicant<br>of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant Figures<br>Appear |
|           | A01    | 5,976,141       | 11/02/99         | Haag et al.  |   |
|           | A02    | 6,575,975       | 06/10/03         | Brace et al.                                       |   |
|           | A03    |                 |                  |  |   |
|           | A04    |                 |                  |  |   |

| *Examiner<br>Initials |     | Foreign Patent Document<br>Country Code, Number,<br>Kind Code (if known) | Date<br>mm/dd/yy | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear | т |
|-----------------------|-----|--|------------------|---|---|---|
| imuais                | B01 | WO 96/25892  | 08/29/96         | Synthes (USA)                                   | r igui es rappeai   |   |
|                       | B02 |  |                  |   |   |   |
|                       | B03 |  |                  |   |   |   |
| *****                 | B04 |  | <del> </del>     |   |   |   |

| *Examiner<br>Initials |     | Include name of the author (in CAPITAL LETTERS), (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | Т |
|-----------------------|-----|--|---|
|                       | C01 | Defendant's Motion For Leave to Amend Answer To Assert Allegations Of Inequitable Conduct, Civil Action  |   |
|                       |     | No. 03-0084 (E.D. Pa.), dated August 7, 2007.  |   |
|                       | C02 | Brief in Support of Defendants' Motion For Leave To Amend Answer To Assert Allegations Of Inequitable  |   |
|                       |     | Conduct, Civil Action No. 03-0084 (ED. Pa.), dated August 7, 2007.   |   |
|                       | C03 | Amended Answer And Counterclaims Of Defendant, Civil Action No. 03-0084 (E.D. Pa.), dated August 7, 2007.  |   |
|                       | C04 | BRETT R. BOLHOFNER, et al., "The Results Of Open Reduction And Internal Fixation Of Distal Femur   |   |
|                       |     | Fractures Using a Biologic (Indirect) Reduction Technique," Journal of Orthopedic Trauma, Vol. 10, No. 6, pp.  |   |
|                       |     | 372-377, Lippincort-Raven Publishers, Copyright 1996 (attached as Exhibit A to Amended Answer)   |   |
|                       | C05 | USPTO Web Site Record re: Application No. 09/848,251, dated May 22, 2007, listing Paul Bianco and Brian  |   |
|                       |     | Poissant (attached as Exhibit E to Amended Answer)   |   |
|                       | C06 | Information Disclosure Statement bearing docket no. 8932-410, dated May 4, 2001 (attached as Exhibit F to  |   |
|                       | 1   | Amended Answer)  |   |
|                       | C07 | Information Disclosure Statement in Application No. 09/660,287, dated November 13, 2000 (attached as Exhibit   |   |
|                       | 1   | G to Amended Answer)   |   |
|                       | C08 | USPTO Web Site Record re: Application No. 09/660,287, dated May 22, 2007 (attached as Exhibit H to   |   |
|                       |     | Amended Answer)  |   |
|                       | C09 | C. KRETTEK et al, "LISS Less Invasive Stabilization System," AO International Dialogue, Vol. 12, Issue 1, June   |   |
|                       |     | 1999 (attached as Exhibit I to Amended Answer)   |   |
|                       | C10 | KENNETH J. KOVAL, et al., "Distal Femoral Fixation: A Biomechanical Comparison of the Standard Condylar  |   |
|                       |     | Buttress Plate, A Locked Buttress Plate, And The 95 Degree Blade Plate," Journal Of Orthopedic Trauma,   |   |

NYI-4019895v1

**EXAMINER** 

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Sheet 2 of 2

| LIST | <b>OF</b> | REFERENCES | CITED B | $\mathbf{Y} \mathbf{A}$ | PPLICANT |
|------|-----------|------------|---------|-------------------------|----------|
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(Use several sheets if necessary)

|                    | 3               |
|--------------------|-----------------|
| ATTY. DOCKET NO.   | APPLICATION NO. |
| 8932-807-999       | 10/665,431      |
| APPLICANT          |                 |
| WEAVER et al.      |                 |
| FILING DATE        | ART UNIT        |
| September 22, 2003 | 3733            |

| *Examiner<br>Initials |     | Include name of the author (in CAPITAL LETTERS), (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | Т |
|-----------------------|-----|---|---|
|                       |     | Volume 11, Issue 7, pp. 521-524, October 1997, Lippincott-Raven Publishers (attached as Exhibit J to Amended Answer)  |   |
|                       | CII | "Less Invasive Stabilization System (LISS) Technique Guide," Synthes (USA) Copyright 2000 (attached as Exhibit K to Amended Answer)   |   |
|                       | C12 | Printout of <a href="http://www.aofoundation.org">http://www.aofoundation.org</a> web site, dated May 23, 2007 (attached as Exhibit L to Amended Answer)  |   |
| <u>-</u>              | C13 | C. KRETTEK, et al., "LISS: Less Invasive Stabilization System," AO Dialogue, 1999 (attached as Exhibit M to Amended Answer)   |   |
|                       | C14 | Printout from USFDA 510(k) Premarket Notification Database, dated May 23, 2007, listing Synthes Distal Femur Plate (DFP) System, and bearing 510(k) number K982222 (attached as Exhibit N to Amended Answer)                              |   |
|                       | C15 | 510(k) Summary For Synthes (USA)'s Distal Femur Plate (DFP) System (K982222), dated July 29, 1998 (attached as Exhibit O to Amended Answer)   |   |
|                       | C16 | Printout from USFDA 510(k) Premarket Notification Database, dated May 22, 2007, listing Synthes Anatomical Locking Plate System, and bearing 510(k) number K961413 (attached as Exhibit P to Amended Answer)                              |   |
|                       | C17 | 510(k) Summary For Synthes (USA)'s Anatomical Locking Plate System (K961413), dated August 7, 1996 (attached as Exhibit Q to Amended Answer)  |   |
|                       | C18 | Printout from USFDA 510(k) Premarket Notification Database, dated May 22, 2007, listing Synthes 2.4 mm Universal Locking Plate System, and bearing 510(k) number K961421 (attached as Exhibit R to Amended Answer)                        |   |
|                       | C19 | 510(k) Summary For Synthes (USA)'s 2.4 mm Universal Locking Plate System (K961421), dated June 26, 1996 (attached as Exhibit S to Amended Answer)   |   |
|                       | C20 | Synthes' Response To Motion For Leave to Amend Answer, Civil Action No. 03-0084 (E.D. Pa.), dated August 9, 2007  |   |

NYI-4019895v1

**EXAMINER** 

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.